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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/635,433	08/10/00	NOE	M PC10491A

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EXAMINER	
MCKENZIE, T	
ART UNIT	**PAPER NUMBER**
1624	4

DATE MAILED: 01/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/635,433	NOE ET AL.	
	Examiner	Art Unit	
	Thomas C McKenzie,Ph.D.	1624	

-- The MAILING DATE of this communication app ars on the cover sh t with th correspond nce addr ss --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-15 & 21-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. This action is in response to an application filed on 8/10/00. There are twenty-three pending claims. Claims 1-13 and 21 are compound claims. Claims 14-20 are use claims. Claims 22 and 23 are composition claims. The application concerns some piperidine and piperazine sulfonamides. This is thew first action on the merits.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 3, drawn to piperazines, compounds of formula I with X = nitrogen, classified in class 544, subclass 383.

II. Claims 2 and 4-12, drawn to piperidines, compounds with X = carbon, with at least one of R^1-R^4 = hydroxyl, classified in class 546, subclass 221.

III. Claims none, drawn to piperidines, compounds with X = carbon, with of R^1-R^4 = hydrogen and methyl, classified in class 546, subclass 227.

IV. Claims 16-20, drawn to a method of treatment, classified in class 514, subclass 1 among others.

Claims 1, 13-15, 22, and 23 link Groups I and II. Claim 21 links Groups II and III.

3. The inventions are distinct, each from the other because of the following reasons: inventions I and II-IV have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Groups II-IV. The basic names of the heterocycles of Group I differ from those of Groups II and III, thus the literature search for these various species will be divergent. Inventions I-III and IV are related as product and process of use. The inventions can be shown to be distinct if following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product (MPEP § 806.05(h)). In the instant case claims 16-20 are independent claims reading on any molecule with the desired pharmacological property and are not restricted to the molecules of claims 1-13. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Garth Butterfield on 1/18/00, a provisional election was made with traverse to prosecute the invention of Group IV, claims 16-20. Applicant in replying to this Office action must make affirmation of this election. Claims 1-15 and 21-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The specification needs to be amended. According to MPEP 201.11, when a non-provisional application is entitled to an earlier U.S. effective filing date of one or more provisional applications under 35 USC 119(e), a statement such as, "This application claims the benefit of U.S. Provisional Application No. 60/------, filed ----." should appear as the first sentence of the specification.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a medical condition of the type characterized by the destruction of articular cartilage" is indefinite. The

claims provide for the use of compounds, but the claims do not set forth any steps involved in determining how to identify "a medical condition of the type characterized by the destruction of articular cartilage". It is unclear what diseases and treatments applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how to practice this use. Must this pathology be the only one associated with the claimed disease? Must it be a major component of the disease process? Must the named pathology be a causative factor in the disease or are diseases that have "destruction of articular cartilage" as an indirect secondary effect also covered? Identifying which diseases applicants intend this claim to cover will involve extensive and potentially inconclusive clinical research. With out such clinical research to identify the patients and diseases applicants intend to treat, one skilled in the art cannot determine the metes and bounds of the claim. Hence, the claims are indefinite.

The phrase "a small molecule" is indefinite. There is no generally accepted definition of the concept in the chemical arts. The chemical biologist considers any molecule not a biological macromolecule a "a small molecule". Thus, any molecule of less than ten thousand molecular weight would qualify. The protein chemist considers any peptide fragment of his proteins to be a small molecule. Thus, compounds of molecular weight one thousand would qualify. The medicinal

chemist has a rule of thumb that molecules around molecular weight 500 are the upper limit for practical medicinal use. The theoretician using extended high order basis sets for *ab* initio calculations would consider anything larger than ethane as too large to handle. Molecular weight is only one measure of size. Could molecular size be determined by volume, length, atomic number of constituent atoms, or complexity?

Allowable Subject Matter

8. Claims 16-20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: Structural formulas, names, or both can accurately describe organic compounds, which are the subject matter of non-elected claims 1-13 and 21. Attempting to define means by function is not proper when the means can be clearly expressed in terms that are more precise. Where means plus function language is used to define the characteristics of a chemical compound, claim limitations are interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof." (Two *en banc* decisions of the Federal Circuit have made clear that the Office is to interpret means plus function language according to 35

U.S.C. 112, sixth paragraph. In the first, *In re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845 the court held: "The plain and unambiguous meaning of paragraph six is that one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure. Paragraph six does not state or even suggest that the PTO is exempt from this mandate, and there is no legislative history indicating that Congress intended that the PTO should be. Thus, this court must accept the plain and precise language of paragraph six."

In the second decision, *In re Alappat* 31 USPQ2d 1545, the Federal Circuit held: "[g]iven Alappat's disclosure, it was error for the Board majority to interpret each of the means clauses in claim 15 so broadly as to "read on any and every means for performing the function" recited ...".

Thus, activity of the disclosed subject matter of the present specification in inhibition of either aggrecanase or collagenase is not anticipated or made obvious by the prior art. Robinson ('361), Reiter ('392), and Duan ('336) all disclose potent inhibitors of aggrecanase, make therapeutic claims, but do not disclose such activity with compounds disclosed in the present application. Bender ('653) and Broka ('220) disclose compounds with potent collagenase inhibitory activity, make

therapeutic claims, and are understandably silent about aggrecanase because aggrecanase was not known at the effective date of filing of Bender ('653) and Broka ('220). However, Bender ('653) teaches such activity with (4-phenoxyphenyl)sulfonyl compounds not the (4-benzyloxyphenyl)sulfonyl compounds disclosed by Applicants. Broka ('220) teaches such activity with (piperidinesulfonyl)piperazine compounds not the (4-benzyloxyphenyl)sulfonylpiperazine compounds disclosed by Applicants.

Conclusion

9. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

TCMcK
January 19, 2001

JOHN M. FORD
PRIMARY EXAMINER
GROUP 1200 - ART UNIT 1624